COJK

PCT/JP2004/006100

# PATENT COOPERATION TREATY

From the INTERNATIONAL BUREAU

# PCT

NOTIFICATION OF TRANSMITTAL
OF COPIES OF TRANSLATION
OF THE INTERNATIONAL PRELIMINARY REPORT
ON PATENTABILITY
(CHAPTER I OR CHAPTER II
OF THE PATENT COOPERATION TREATY)

(PCT Rules 44*bis*.3(c) and 72.2)

To:

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| | |
|---|---|
| Date of mailing *(day/month/year)*<br>09 March 2006 (09.03.2006) | |
| Applicant's or agent's file reference<br>sankyoFP0412 | **IMPORTANT NOTIFICATION** |
| International application No.<br>PCT/JP2004/006100 | International filing date *(day/month/year)*<br>27 April 2004 (27.04.2004) |
| Applicant<br>SANKYO COMPANY, LIMITED et al | |

1. **Transmittal of the translation to the applicant.**

☐ The International Bureau transmits herewith a copy of the English translation of the international preliminary report on patentability (Chapter I).

☑ The International Bureau transmits herewith a copy of the English translation of the international preliminary report on patentability (Chapter II).

2. **Transmittal of the copy of the translation to the designated or elected Offices.**

The International Bureau notifies the applicant that copies of that translation have been transmitted to the following designated or elected Offices requiring such translation:

EP, KR

The following designated or elected Offices, having waived the requirement for such a transmittal at this time, will receive copies of that translation from the International Bureau only upon their request:

AE, AG, AL, AM, AP, AT, AU, AZ, BA, BB, BG, BR, BW, BY, BZ, CA, CH, CN, CO, CR, CU, CZ, DE, DK, DM, DZ, EA, EC, EE, EG, ES, FI, GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KP, KZ, LC, LK, LR, LS, LT, LU, LV, MA, MD, MG, MK, MN, MW, MX, MZ, NA, NI, NO, NZ, OA, OM, PG, PH, PL, PT, RO, RU, SC, SD, SE, SG, SK, SL, SY, TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ, VC, VN, YU, ZA, ZM, ZW

3. **Reminder regarding translation into (one of) the official language(s) of the elected Office(s).**

The applicant is reminded that, where a translation of the international application must be furnished to an elected Office, that translation must contain a translation of any annexes to the international preliminary report on patentability (Chapter II).

**It is the applicant's responsibility to prepare and furnish such translation directly to each elected Office concerned within the applicable time limit (Rule 74.1). See Volume II of the PCT Applicant's Guide for further details.**

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|---|---|
| The International Bureau of WIPO<br>34, chemin des Colombettes<br>1211 Geneva 20, Switzerland | Authorized officer<br>Yoshiko Kuwahara |

Translation

# PATENT COOPERATION TREATY

# PCT

## INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

(Chapter II of the Patent Cooperation Treaty)

(PCT Article 36 and Rule 70)

| Applicant's or agent's file reference | FOR FURTHER ACTION | See Form PCT/IPEA/416 |
|---|---|---|
| sankyoFP0412 | | |
| International application No. | International filing date (*day/month/year*) | Priority date (*day/month/year*) |
| PCT/JP2004/006100 | 27.04.2004 | 28.04.2003 |
| International Patent Classification (IPC) or national classification and IPC | | |
| Applicant | | |
| SANKYO COMPANY, LIMITED | | |

1. This report is the international preliminary examination report, established by this International Preliminary Examining Authority under Article 35 and transmitted to the applicant according to Article 36.

2. This REPORT consists of a total of 6 sheets, including this cover sheet.

3. This report is also accompanied by ANNEXES, comprising:

   a. ☐ (*sent to the applicant and to the International Bureau*) a total of _____ sheets, as follows:

      ☐ sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications authorized by this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions).

      ☐ sheets which supersede earlier sheets, but which this Authority considers contain an amendment that goes beyond the disclosure in the international application as filed, as indicated in item 4 of Box No. I and the Supplemental Box.

   b. ☐ (*sent to the International Bureau only*) a total of (indicate type and number of electronic carrier(s))

      _____, containing a sequence listing and/or tables related thereto, in computer readable form only, as indicated in the Supplemental Box Relating to Sequence Listing (see Section 802 of the Administrative Instructions).

4. This report contains indications relating to the following items:

- ☒ Box No. I Basis of the report
- ☐ Box No. II Priority
- ☒ Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- ☐ Box No. IV Lack of unity of invention
- ☒ Box No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- ☐ Box No. VI Certain documents cited
- ☐ Box No. VII Certain defects in the international application
- ☐ Box No. VIII Certain observations on the international application

| Date of submission of the demand | Date of completion of this report |
|---|---|
| Name and mailing address of the IPEA/JP<br><br>Facsimile No. | Authorized officer<br><br>Telephone No. |

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

International application No.
PCT/JP2004/006100

**Box No. I Basis of the report**

1 With regard to the **language**, this report is based on the international application in the language in which it was filed, unless otherwise indicated under this item

☐ This report is based on translations from the original language into the following language _____, which is the language of a translation furnished for the purposes of:

☐ international search (Rule 12.3 and 23.1(b))

☐ publication of the international application (Rule 12.4)

☐ international preliminary examination (Rule 55.2 and/or 55.3)

2 With regard to the **elements** of the international application, this report is based on *(replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report)*:

☒ the international application as originally filed/furnished

☐ the description:

pages _____ as originally filed/furnished

pages* _____ received by this Authority on _____

pages* _____ received by this Authority on _____

☐ the claims:

nos. _____ as originally filed/furnished

nos.* _____ as amended (together with any statement) under Article 19

nos.* _____ received by this Authority on _____

nos.* _____ received by this Authority on _____

☐ the drawings:

sheets _____ as originally filed/furnished

sheets* _____ received by this Authority on _____

sheets* _____ received by this Authority on _____

☐ a sequence listing and/or any related table(s) – see Supplemental Box Relating to Sequence Listing

3 ☐ The amendments have resulted in the cancellation of:

☐ the description, pages _____

☐ the claims, nos. _____

☐ the drawings, sheets/figs _____

☐ the sequence listing *(specify)*: _____

☐ any table(s) related to sequence listing *(specify)*: _____

4 ☐ This report has been established as if (some of) the amendments annexed to this report and listed below had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).

☐ the description, pages _____

☐ the claims, nos. _____

☐ the drawings, sheets/figs _____

☐ the sequence listing *(specify)*: _____

☐ any table(s) related to sequence listing *(specify)*: _____

* *If item 4 applies, some or all of those sheets may be marked "superseded."*

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

International application No.
PCT/JP2004/006100

**Box No. III** **Non-establishment of opinion with regard to novelty, inventive step and industrial applicability**

The questions whether the claimed invention appears to be novel, to involve an inventive step (to be non obvious), or to be industrially applicable have not been examined in respect of:

☐ the entire international application

☒ claims Nos. 41-57

because:

☒ the said international application, or the said claims Nos. 41-57 relate to the following subject matter which does not require an international preliminary examination (*specify*):

The subject matter of claims 41 to 57 pertains to a method of treatment of the human body by therapy.

☐ the description, claims or drawings (*indicate particular elements below*) or said claims Nos. _____ are so unclear that no meaningful opinion could be formed (*specify*):

☐ the claims, or said claims Nos. _____ are so inadequately supported by the description that no meaningful opinion could be formed.

☒ no international search report has been established for said claims Nos. 41-57

☐ the nucleotide and/or amino acid sequence listing does not comply with the standard provided for in Annex C of the Administrative Instructions in that:

the written form
- ☐ has not been furnished
- ☐ does not comply with the standard

the computer readable form
- ☐ has not been furnished
- ☐ does not comply with the standard

☐ the tables related to the nucleotide and/or amino acid sequence listing, if in computer readable form only, do not comply with the technical requirements provided for in Annex C-*bis* of the Administrative Instructions.

☐ See Supplemental Box for further details.

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

International application No
PCT/JP2004/006100

**Box No. V** Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1 Statement

| | | | |
|---|---|---|---|
| Novelty (N) | Claims | 1-20, 25-28 | YES |
| | Claims | 21-24, 29-40 | NO |
| Inventive step (IS) | Claims | 1-10 | YES |
| | Claims | 11-40 | NO |
| Industrial applicability (IA) | Claims | 1-40 | YES |
| | Claims | | NO |

2 Citations and explanations (Rule 70.7)

Documents cited in the international search report:

Document 1: McFarlane S.I. et al., J Clin Endocrinol Metab. April 2002; 87(4): 1451 to 8

Document 2: Toru Komai, Bio Clin, Vol. 17, No. 10; pages 918 to 923, 10 September 2002

Document 3: WO 00/56403 A1 & JP 2003-511347 A

Document 4: WO 01/76573 A2 & JP 2003-530342 A

Document 5: JP 9-071540 A

Document 6: Bellosta S. et al., Diabetes Care, 23 April 2000, Suppl. 2: B72-8

Document 7: Ichiro Shimomura et al., Gekkan Medical Science Digest, 28 (12), pages 479 to 482; 25 November 2002

Document 8: Toru Funabashi et al., "Naika", Vol. 89, No. 5, pages 849 to 854; 1 May 2002

Claims 11 to 20 and 33 to 36

Documents 1 and 2 set forth the relation between saccharometabolism and HMG-CoA reductase inhibitors. In the light of these documents it would be easy for a person skilled in the art to apply an HMG-CoA reductase inhibitor to the treatment of disorders related to saccharometabolism, such as diabetes.

Therefore the invention set forth in claims 11 to 29 and 33 to 36 does not involve an inventive step.

Claims 21 to 24 and 33 to 40

Document 3 sets forth the treatment of pulmonic hypertension using an HMG-CoA reductase inhibitor. Pulmonic hypertension is a type of hypertension, therefore document 3 sets forth an invention which cannot be distinguished from the invention set forth in claims 21 to 24 and 33 to 40 of this application. In addition, taking into account the fact that the production of NO within the endothelium is increased by HMG-CoA reductase inhibitors, it would be easy for a person skilled in the art to consider applying an HMG-CoA reductase inhibitor to other types of hypertension.

Therefore the invention set forth in claims 21 to 24 and 33 to 40 lacks novelty and does not involve an inventive step.

Claims 29 to 40

Documents 1, 5 and 6 set forth a relation between HMG-CoA reductase inhibitors and arterial sclerosis.

Therefore the invention set forth in claims 29 to 40 lacks novelty and does not involve an inventive step.

Claims 11 to 40

Document 4 indicates that HMG-CoA reductase inhibitors are used in conjunction with other medications in the treatment of various disorders. It would be easy for a person skilled in the art to consider the independent effects of medications used in conjunction with HMG-CoA reductase inhibitors in document 4, in the

aforementioned treatment of different types of disorders.

Therefore the invention set forth in claims 11 to 40 does not involve an inventive step.

Claims 1 to 10

Documents 1 to 8 neither indicate nor suggest that the production of adiopectin is increased by HMG-CoA reductase inhibitors.

Therefore the invention set forth in claims 1 to 10 is novel and involves an inventive step.